इंटरनेट मानक

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IS 8432 (1977): Tubes, Tracheotomy (rubber or plastics) [MHD 13: Veterinary Hospital Planning and Surgical Instruments]

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Indian Standard

(Reaffirmed 1998)

SPECIFICATION FOR TUBES, TRACHEOSTOMY (RUBBER OR PLASTICS)

Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, CPDC 13; Anaesthetic, Oxygen and Inhalation Therapy Equipment Subcommittee, CPDC 13 : 1
[Ref : Doc : CPDC 13 (975)]

1. Scope — Dimensional and other requirements for tracheostomy tubes with or without cuffs, made of rubber or plastics to by-pass upper airway obstruction.

2. Materials

2.1 Tracheostomy tubes, including cuffs, in their ready-for-use state shall be compatible with the human tissue without causing toxic, allergic or inflamatory reaction.

2.2 Unless designated as disposable, tracheostomy tubes shall be reasonably resistant to deterioration by methods of cleaning, disinfection and sterilization as recommended by the manufacturer or the supplier. It is desirable that such tubes shall withstand accepted methods of sterilization. The recommended method or methods of sterilization shall not produce changes in the tube material which will render the tracheostomy tube incompatible with human tissue (*see also* **2.1**).

2.3 Tracheostomy tubes shall be resistant to anaesthetic vapours and gases.

2.4 The material shall have sufficient rigidity to allow the construction of a tube with the thinnest possible wall and at the same time prevent kinking. When not in use, the specified radius of curvature of the tube shall be maintained within reasonable limits. When in place, it shall be flexible and soft enough to conform to the patient's anatomy without exerting undue pressure on the body tissues.

3. Shape and Dimensions — As shown in Fig. 1 and 2.

3.1 The inflating tube, if fitted, shall have an external diameter of not more than 3·0 mm. The free end of the inflating tube may be opened or sealed with an appropriate plug or valve. Where the end is open, it shall have a female conical shape and capable of fitting to the male conical fitting with a 6 percent taper (Luer) in accordance with IS : 3234-1965 'Specification for conical fitting for hypodermic syringes, needles and other medical equipment, Luer type '.

3.2 The tube shall be easy to connect with accessory equipment.

3.3 A deviation of ±2·5 percent shall be allowed on all dimensions.

4. Size Designation

4.1 The size of the tracheostomy tube shall be designated by a number giving the nominal internal diameter expressed in millimetres.

5. Workmanship and Finish

5.1 The tracheostomy tubes shall be smooth externally and internally. The cuffs shall have a smooth surface.

5.2 The end of the tube shall be round and there shall not be any sharp point at the edge.

5.3 The cuff, if fitted, shall be capable of reasonably symmetrical expansion, when the cuff is inflated with air to a diameter of 1·5 times the external diameter of the tube.

5.4 The inflating tube shall be attached to the parent tube and shall join the cuff in such a manner as to ensure that there is no undue projection to interfere with the clinical use of the tube.

5.5 The inflating tube may be provided with a pilot balloon (*see* Fig. 2). The pilot balloon when deflacted shall lie flat and shall be so constructed as to give adequate indication of the inflation of the cuff at the pressure required to distend the cuff to one and a half times of external diameter of the tube.

5.6 The tube shall be uniformly circular and concentric in section and have uniform bore. The tubing shall be non-porous, of homogeneous character throughout and free from grit, pitting, loose dusting agents, blooming and other visible defects.

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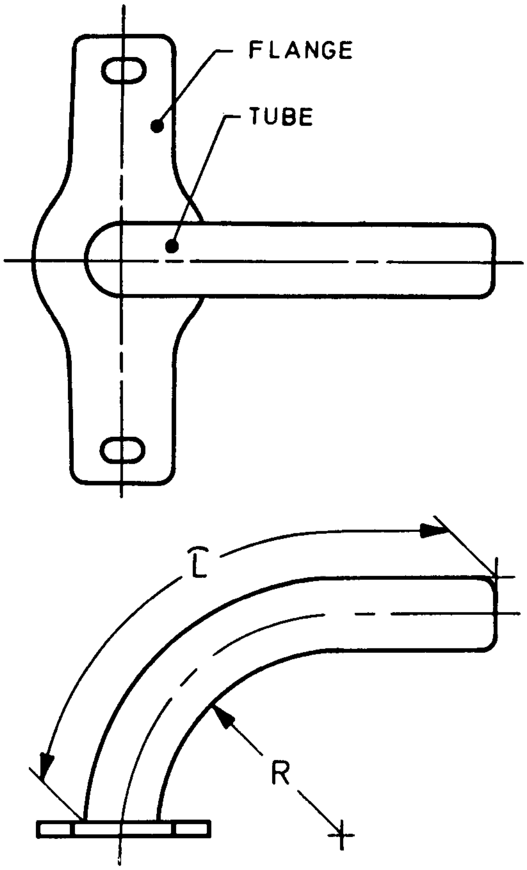


Size	Inner Dia	Outer Dia	*R*, Curvature	*L*, Length
1	4·5	6·0	17·5	60
2	5·3	7·0	20·0	62
3	6·0	8·0	21·0	63
4	6·7	9·0	17·5	70
5	7·4	10·0	31·0	80
6	8·2	11·0	20·5	90
7	8·9	12·0	26·5	92
8	9·6	13·0	31·0	93
9	10·4	14·0	31·0	100

All dimensions in millimetres.

FIG. 1 TUBE TRACHEOSTOMY, PLAIN, WITHOUT CUFF

5.7 When the cuff is inflated the internal diameter of the parent tube shall not be affected.

6. Marking

6.1 *Marking Materials* — Marking materials used on tracheostomy tube shall be compatible with human tissue with which the tubes are intended to be used and shall resist anaesthetic agents and agents commonly used in cleaning and sterilizing.

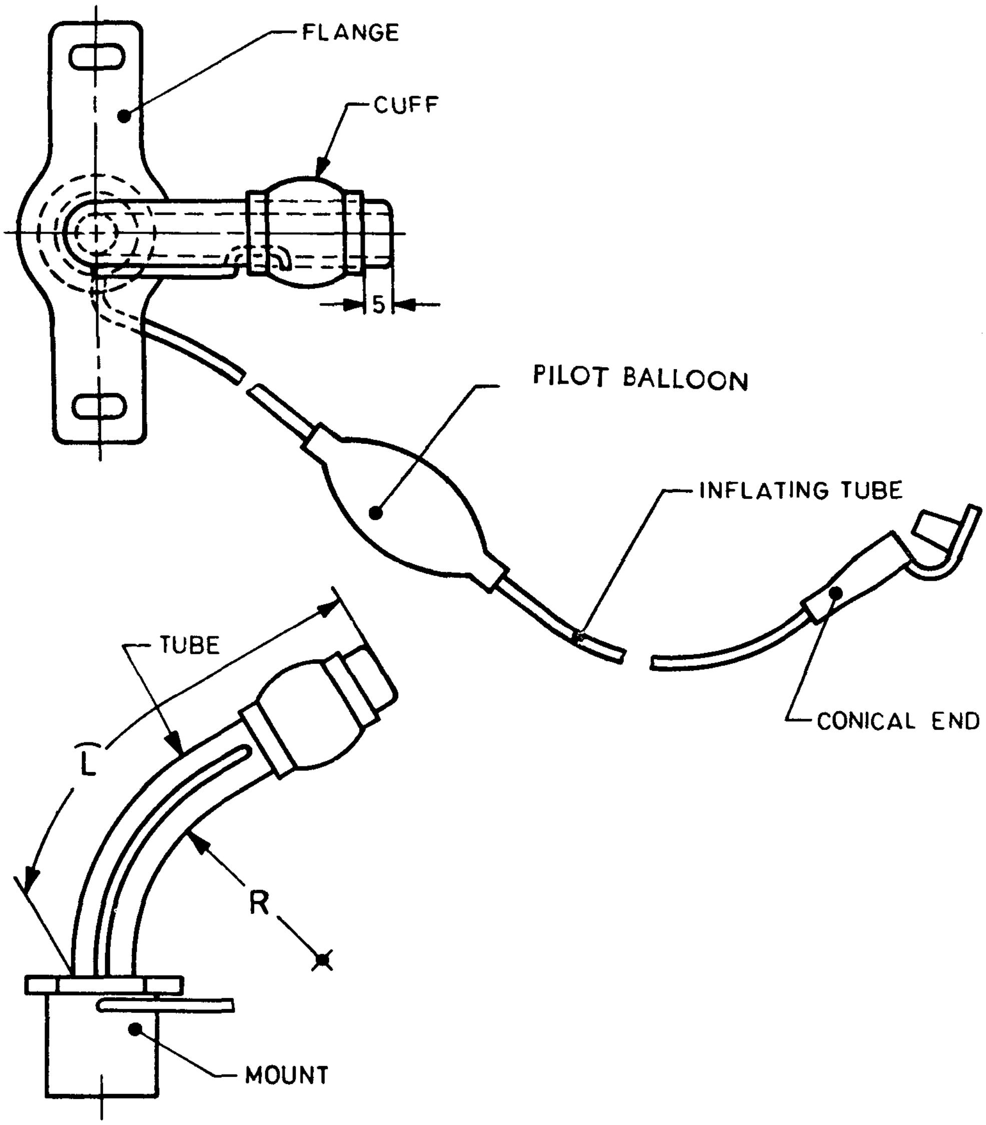
6.2 The tracheostomy tube shall be legibly and indelibly marked with the following:

a) The name or trade-mark of the manufacturer; and

b) Size number in accordance with **4.1**.

6.3 Disposable tracheostomy tubes shall be clearly marked ' Disposable ' or in a manner as agreed to between the purchaser and the supplier.

6.4 *ISI Certification Marking* — Details available with the Indian Standards Institution.



Size	Inner Dia	Outer Dia	*R*, Curvature	*L*, Length
1	6·0	8·0	26·0	62
2	6·7	9·0	17·5	70
3	7·4	10·0	31·0	82
4	8·2	11·0	20·5	94
5	8·9	12·0	26·5	101
6	9·6	13·0	21·5	102
7	10·4	14·0	22·0	105

All dimensions in millimetres.

FIG. 2 TUBE TRACHEOSTOMY, WITH CUFF

7. Packing and Storage — The tubes shall be packed as agreed to between the purchaser and the supplier. The tubes shall be stored in a cool dark place, preferably in a rigid container in which the tubes are not likely to be subjected to mechanical damage. The number of tubes kept in one container shall be limited in order to avoid deformation of any tube either by crushing or by the formation of kinks. The tubes shall not be allowed to come into contact with oil based antiseptic phenols and their derivatives, petroleum-based grease, petroleum spirit paraffin (kerosine) or other related organic products, since all these materials are extremely harmful to rubber.

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